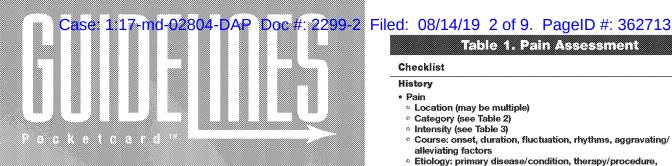
Case: 1:17-md-02804-DAP Doc #: 2299-2 Filed: 08/14/19 1 of 9. PageID #: 362712

PSJ15 Exh 35



Managing:

**Appropriate Use of Opioids** 

Version 1.0

#### **Medical Consultant**

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#### Table 1. Pain Assessment

#### Checklist

#### History

- e Pain
  - · Location (may be multiple)
- · Category (see Table 2)
- o Intensity (see Table 3)
- · Course: onset, duration, fluctuation, rhythms, aggravating/ alleviating factors
- Etiology: primary disease/condition, therapy/procedure, comorbidities
- Effects of pain on patient
- · Impaired functioning (physical, mental), quality of life
- · Accompanying symptoms (e.g., nausea, impaired sleep, loss of appetite, decreased activity)
- · Emotional distress (e.g., crying, angry, anxious, depressed,
- · Impaired relationships (e.g., family, school, occupational, social)
- Psychiatric or substance abuse history
- Patient/family/significant others' knowledge and beliefs about pain
- Communication barriers: minority/cultural factors
- · Litigation or worker's compensation
- · Special populations (e.g., pediatric, geriatric, pregnancy/lactation, substance abuse/addiction, cognitive impairment)

Relevant laboratory and imaging studies based on data from patient history and examination

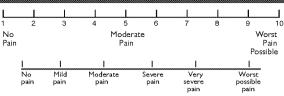
### Table 2. Categories of Pain\*

- Acute (eudynia): usually related to an identifiable trauma or medical condition; resolution within days or weeks as condition resolves.
- . Chronic (maldynia): may/may not be related to identifiable pathology; may persist indefinitely; frequently associated with mood disturbances, physical dysfunction, social disruption.
- · Neuropathic: acute or chronic pain resulting from peripheral or central nervous system pathology; described as sharp, shooting, tingling, and/or burning, electric; often associated with neurological deficits.
- · Nociceptive: acute or chronic pain related to tissue damage, involving direct stimulation of intact nociceptors, and relayed along normally functioning nerves.
- . Somatic (from skin, soft tissue, muscle, bone); sharp/stabbing, aching, and/or throbbing pain-easily localized.
- · Visceral (from internal organs): gnawing, cramping, deep, and/or pressing pain difficult to describe and localize; may be concurrent nausea, vomiting, or diarrhea.

Adapted from: Emanual LL, von Gunten CF, Ferris FD. The Education for Physicians on End-of Life Care (EPEC) curriculum. Module 4, Pain Mangement. EPEC Participant's Handbook. EPEC Project. Princeton, NJ: The Robert Wood Johnson Foundation; 1999.

<sup>\*</sup>In documentation, use patient's own words to describe pain.

### Table 3. 1–10 Numeric Fain Rating and Intensity Scale



From: Acute Pain Management: Operative or Medical Procedures and Trauma, Clinical Practice Guadeline No. 1, AHCPR Publication No. 92-0032; February 1992. Agency for Healthcare Research & Quality, Rockville, MD; pages 116-117.

#### NO PAIN

MILD PAIN (you know it's there but hardly notice it)

MODERATE PAIN (a little more pain than mild pain – it does not stop you from doing things)

SEVERE PAIN (wakes you from sleep or makes you stop your activity to ease the pain)

VERY SEVERE PAIN (you cannot stand the pain and are unable to do any activity or sleep)

WORST POSSIBLE PAIN (the worst pain you can imagine)

- Reassess at specified intervals and with same scale to evaluate intended effect of therapy.
- Therapeutic goal is satisfactory pain control (usually below 4) with tolerable side effects and acceptable quality of life (physical, psychological, occupational, social functioning).

#### Table 4. Addiction Assessment Tools

#### CAGE-AID (CAGE Adapted to Include Drugs)\*

*	Have you felt you ought to Cut down on your drinking/drug use?	1	Yes	0	No
	Have people Annoyed you by criticizing your drinking/drug use?	1	Yes	0	No
	OR				
	Have people told you about things you said/did while you were drinking/on drugs that you could not remember (Amnesia)?	1	Yes	0	No
	Have you ever felt bad or Guilty about your drinking/drug use?	1	Yes	0	No
•	Have you ever needed a drink/used drugs as an Eye-opener or to steady your nerves first thing in the morning?	1	Yes	0	No

#### TOTAL SCORE OF ≥ 2 CONSIDERED CLINICALLY SIGNIFICANT.

SISAP (Screening Instrument for Substance Abuse Potential)
For predicting addiction riak in patients receiving opioids.
Access at: http://www.stoppain.org/pcd/\_pdf.

#### DAST-20 (Drug Abuse Screening Tool)

For detecting potential drug abuse or dependency disorders in patients.

Access at: http://www.adai.washington.edu/instruments/pdf/DAST.pdf

#### **ORT (Opioid Risk Tool)**

For predicting patients at high and low risk for opioid-related aberrant behavior.

Access at: http://www.lifetreeresearch.com/media/articles/ORT.pdf

SOAPP (Screener and Opioid Assessment for Patients in Pain)
For chronic pain patients being considered for long-term opioid
treatment.

Access at: http://www.painedu.org/soap.asp.

#### Table 5. Principles of Pain Management with Opioids

#### Acute Pain (eudynia)

- · Establish diagnosis and treat underlying conditions.
- Determine associated pain location, intensity, and category (see Tables 1, 2, 3).
- Symptomatic treatment of acute pain should be multimodal, with possible application of:
- Non-pharmacologic approaches (e.g., heat, ice, rest, massage, education)
- Non-opioids (e.g., ASA, APAP, NSAIDs, COXIBs)
- Opioids titrated to effect (see Table 9).
- · Use least invasive route of administration.
- . Treat pain before it becomes severe; dose PRN.
- · Risk of addiction rare (see Table 7).

#### Chronic non-cancer pain (maldynia)

- Establish diagnosis and treat underlying conditions.
- Patients may be considered for therapeutic trial of opioids.
- Complex patients (e.g., addiction, medical problems, psychopathology, rehabilitation issues) may need management in specialty setting.
- Written treatment plan (individualized to patient and pain problem)
   includes:
- Medication(s) (name, dose, frequency)
- Measurable objectives (clinical outcomes)
- Informed consent (risks/benefits of opioid therapy)
- Physician-patient therapeutic agreement (terms/conditions for prescribing opioids)
- Prepare exit strategy for patients failing to meet specific goals of agreedon therapy.

#### Cancer-related pain

- Establish diagnosis and treat underlying conditions.
- Patients may be more tolerant of opioid risks and side effects.
- Pain prevention easier than relieving existing pain for chronic pain, dose ATC with fixed dose, plus PRN doses for breakthrough pain.
- Appropriate opioid dose can relieve pain throughout dosing interval without unmanageable side effects — single-entity opioids have no maximum dose but may be limited by side effects.
- Anticipate certain opioid-induced side effects by beginning prophylactic medication when initiating opioid therapy (see Table 6).

#### Rescue dose for breakthrough pain

- Divide standing dose by hourly frequency of standing dose; e.g., 60 mg morphine sulfate (MS) PO q 4 h: 60  $\div$  4 = 15 mg MS q 1 h PRN
- Use same drug as standing drug. If not possible, use equianalgesic dose
  of same class of drug (see Table 9).
- Alternative: 10 15% of 24 h (ATC + PRN) dosage PO q 1 2 h PRN.
- If rescue dose required regularly (in each dosing interval) for > 24 h:
   Increase standing dose by quantity of rescue dose given in dosing interval; e.g., 60 mg MS PO q 4 h with two 15 mg rescues in average 4-h
- period: 60 mg + 30 mg = 90 mg MS q 4 h;
  Increase rescue dose: 90 ÷ 4 = 22 mg MS (elixir) q 1 h PRN.

#### ALL PATIENTS

- · Periodic review
- · Pain rating (intensity, category, location)
- Treatment effectiveness (goal established on 0 10 pain intensity scale)
- Patient's functional changes
- Side effects/adverse effects
- · Patient adherence to regimen
- Diligently documented medical records include:
- Patient visits
- Specialty consults
- · Therapeutic/diagnostic procedures, lab results
- Prescriptions (e.g., date, drug, strength, dosage units, route of administration, frequency)
- Document the 4 A's (Analgesia, Activity, Adverse Side Effects, and Aberrant Behavior)\*
- \* Passik SD, Weinreb H.J. Managing chronic nonmalignant pain: overcoming obstacles to the use of opioids. Adv Ther. 2000;17:70-83. Passik SD, Kirsh KL, Whitcomb L, et al. Pain clinicians' rankings of aberrant drug-taking behaviors. J Pain Palliat Care Pharmacother. 2002;16:39-49

Adapted from: Model Guidelines for the Use of Controlled Substances for the Treatment of Pain Euless, TX. Federation of State Medical Boards of the United States, Inc.; 1998. Pocket Guide for Pain Management in Adults. Boston, MA: Tufts-New England Medical Center; 1998. Scott CI, Griffin CB, eds. Pain Management Tables and Guidelines: Pain and Symptom Management. Boston, MA: Brigham and Women's Hospital; 2000.

<sup>\*</sup>Adapted from: Brown RL, Rounds, LA. Conjoint screening questionnaire for alcohol and drug abuse. Wis Med J 1995;94:135–140.

Critical to distinguish tolerance, dependence, and psuedo-addiction from addiction (see Table 7).

Adverse Effeqse: 1:17-md-02804-	Table 6. Management of Opioid Side Effects  OAP Doc.#: 2299-2 Filed: 08/14/19 4 of 9. PageID #: 362715
Confusion/Delirium	<ul> <li>Assess for other causes (e.g., other psychoactive agents, CNS pathology); check electrolytes, calcium, glucose</li> <li>Consider metabolic accumulation</li> <li>Consider adding non-opioid analgesic or consult specialist for interventional technique to achieve opioid dose reduction</li> <li>Consider changing opioid (See Table 8)</li> <li>Consider neuroleptic agent (e.g., olanzapine, risperidone)</li> </ul>
Constipation (begin bowel regimen at onset of opioid therapy; goal is frequency/quality of movement acceptable to patient; tolerance does not develop)	<ul> <li>Increase fluids; exercise (when appropriate)</li> <li>Initiate stimulant laxative* (e.g., senna, casanthranol) + stool softener (docusate) taken at fixed daily dose; consider increasing laxative dose when increasing opioid dose (opioid constipation is dose dependent)</li> <li>Consider adding non-opioid analgesic to allow opioid dose reduction</li> <li>Rectal examination to check for impaction; if found, disimpact</li> <li>Consider adding another agent (e.g., magnesium hydroxide, bisacodyl, rectal suppository, lactulose, sorbitol, magnesium citrate; Fleet, saline, or water enema) when needed</li> <li>Consider prokinetic agent (e.g., metoclopromide)</li> </ul>
Nausea/Vomiting (prescribe antiemetics with initial opioid prescription; tolerance may develop)	<ul> <li>Assess for other causes (e.g., constipation/obstruction, CNS pathology, chemotherapy, radiation therapy)</li> <li>Antiemetic ATC for few days to 1 week, then PRN (e.g., prochlorperazine, thiethylperazine, metoclopromide, droperidol, ondansetron, haloperidol)</li> <li>Consider adding non-opioid medication to achieve opioid dose reduction</li> <li>Consider changing opioid or route of administration</li> </ul>
Pruritis	Consider antihistamine (e.g., diphenhydramine, cetirizine, fexofenadine, doxepin)     Consider switching opioids
Respiratory depression, hypoventilation (tolerance often develops with chronic use)	If respiratory rate falls below 10, shallow breathing, or unresponsive to voice/stimulation, as appropriate:  Consider comfort measures if patient is terminal and DNR  Assure patient airway; initiate supportive respiratory measures (e.g., jaw lift, AMBU bag) – if patient is not terminal or DNR  Consider naloxone if life-threatening: dilute 0.4 mg naloxone with 9 mL saline and administer in 0.04 (1 mL) increments until respiratory rate > 8 – 10/min; use cautiously to avoid withdrawal symptoms and severe pain  Hold further doses of opioids until episode resolves
Sedation (tolerance often develops with chronic use)	Assess degree of sedation, and as appropriate:  Assess for other causes (e.g., other psychoactive agents, hypercalcemia, CNS pathology, metastases, sepsis)  Consider addition of caffeine, methylphenidate, dextroamphetamine, modafinil  Consider titrating opioid dose downward to reduce sedation (if pain control can be maintained)  Consider non-opioid analgesic to achieve opioid dose reduction  Consider lower opioid dose administered – consistent with duration of action – could drive prescribing q 8h  Consider changing opioid

<sup>\*</sup>If long-term use anticipated, use cautiously because of possibility of dependence.

Adapted from: Use of Opioid Analgesics for the Treatment of Chronic Noncancer Pain—A Consensus Statement and Guidelines. Canadian Pain Society; 1998. Cherny N, Ripamonti C, Pereira J, et al for the Expert Working Group of the European Association of Palliative Care Network. Strategies to manage the adverse effects of oral morphine: an evidence-based report. J Clin Oncol 2001;19:2542–2554. McNicol E, Horowicz-Mehler N, Fisk RA, et al. Management of opioid side effects in cancer-related and chronic noncancer pain—a systematic review. J Pain 2003;4:231–256.

Table 7. Analgesic Tolerance, Dependence, Addiction									
Term	Definition	Comments							
Tolerance	Neuroadaptation to effects of chronically administered opioids, requiring increasing doses to maintain analgesia or decreasing analgesia over time.	<ul> <li>Not in itself predictive/diagnostic of addiction</li> <li>Treatment not required if dose stabilizes</li> <li>Treatment includes changing opioids or adding non-opioid analgesic modalities</li> <li>Dosages must be increased to produce the same effect</li> </ul>							
Physical dependence	Physiologic state in which abrupt cessation of opioid, or administration of opioid antagonist, results in withdrawal syndrome: e.g., agitation, tachycardia, hypertension, piloerection, coryza, tremors, sweats, chills, lacrimation, abdominal cramps, arthralgia, myalgia, vomiting, diarrhea, increased pain.	Not in itself predictive/diagnostic of addiction Common state with long-term opioid therapy Treatment not needed for physical dependence Abstinence requires treatment Withdrawal may be avoided by tapering down opioid therapy							
Addiction	Persistent psychological pattern of inappropriate opioid use despite harm to self and others; e.g., compulsive preoccupation with obtaining/using opioids, loss of control over opioid use, lack of concern for adverse consequences of opioid misuse.	Screen patient for risk factors (see Table 4) Review patient medication history Document and evaluate aberrant drug-taking behavior (e.g., chronic early refills, prescription loss, unauthorized dose escalation) Patients with substance abuse/addiction disorders potentially at higher risk for opioid abuse but can be treated with opioids under controlled circumstances; may require specialty referral Addiction treatment requires referral to addiction specialist							
Pseudoaddiction	Drug-seeking behavior focused on pain relief, due to undertreatment of pain.	Behavior normalizes with adequate analgesia							

### Table 8. Opioid Equianalgesic Conversion

- After optimum titration of dose/frequency, consider changing opioid if:
  - o Unachieved control of pain
  - o Inadequate onset/duration of action
  - o Intolerable side effects
  - o Unsatisfactory route of administration
  - o Unacceptable drug-drug interaction
  - o Dissatisfaction of patient
- Step 1 First determine total 24 hour dose of current drug. Locate the dose of the present opioid by the present route listed in the equianalgesic chart (Table 9). Then determine the number of equianalgesic dose units in the 24-hour dose.
   Step 2 Locate the dose of the new opioid by the present route listed on the equianalgesic chart (Table 9)
   Step 3 Determine the 24-hour dose of the new opioid by multiplying the equianalgesic dose units of the present opioid.
- Step 4 Divide the 24-hour dose of the new drug by the number of doses to be given each 24 hours.
- Formula: Current total 24-h opioid dose X Equianalgesic conversion factor for new opioid = Dose of the new opioid every 24 hours Equianalgesic conversion factor for current opioid
- Key Considerations
- 1. All equianalgesic ratios/formulas are approximations; clinical judgment is needed when making dose or drug conversions.
- 2. If the patient is opioid tolerant and has been taking a high dose of opioid, it is best not to abruptly discontinue the present opioid and convert to the new in one step. This could lead to an overdose, causing undesirable side effects, or an under dose, precipitating severe pain. Instead, in these cases, make the transition starting with 50% of the current opioid dose combined with 50% of the projected dose for the new opioid. Gradual increases in the new opioid drug and decreases in the old can be made until the switch is complete over a period of several days. It may be necessary to adjust the dose of the new opioid (ie, maintain the 50% dose of the old opioid and increase the new opioid for insufficient pain relief). Once the combined doses provide good pain control, drop the old opioid and double the new.

Adapted from: Pain, 2nd Edition - Clinical Manual, Margo McCaffery, RN, MS, FAAN: and Chris Pasero, RN, MSNc

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# Case: 1:17-md-02804-DAP\_Doc #: 2299-2\_Filed: 08/14/19\_6 of 9\_PageID #: 362717 Table 9. Opioid Analgesics

Drugs in red are long acting, controlled-release, or long ha	nan-iived.
--------------------------------------------------------------	------------

	Drugs in red are long acting, controlled-release, or long half-lived.								
Drug Generic/Brand	INJ	i	PO	Usual Adult Dose	Dose Adjustment	Clinical Comments			
MU AGONISTS COMMONLY USED FO	R MILD T	о мо	DERATE PAIN						
Tramadol Ultram	NA		50 – 100 mg	PO: 50 – 100 mg q 4 – 6 h Max: 400 mg/d	Lower doses for medically ill and older patients	Action analogous to synthetic codeine; partial non-opioid mecha- nisms of action (antidepressant-like)			
Ultram ER	NA			PO: 100 mg/d initially, increasing in 100 mg increments q 5 d to max 300 mg/d		Caution if seizure risk     Not a scheduled product     Drug interaction with SSRIs and MAOIs			
Ultracet (with APAP)	NA			PO: 75 mg q 4 – 6 h prn Max: 300 mg (2.6 g APAP)/d ≤ 5 d					
MU AGONISTS COMMONLY USED FOR MODERATE TO SEVERE PAIN									
Fentanyl [C II] (0.1 mg = 100 μg) Actiq	NA			Lozenge: 200 µg q 30 min prn titrated increase	Geriatrics: Titrate with caution	Lozenge for breakthrough cancer pain in patients taking ≥ 50 mg of another opioid     Good choice if renal failure     Patch for chronic pain, not for			
Duragesic			NA	Patch: 25 µg/h q 72 h (transdermal 25 µg/h = 50 – 60 mg/24 h oral morphine)		acute, postoperative pain, or mild/ intermittent pain  Buccal tablet for breakthrough cancer pain in opioid-tolerant			
Fentora	NA			Buccal tablet: 100 ug q 30 min prn, titrated in 100 ug increments		patients • Fentanyl-induced thoracic rigidity (FITR) seen with rapid IV administration			
Hydrocodone [C III]  Lorcet HD, Lortab, Vicodin, others with APAP); Lortab ASA, Panasal, others (with ASA);  Vicoprofen (with ibuprofen)	NA		5 – 20 mg	PO: 5 - 10 mg q 4 - 6 h Max: 4 g/d of APAP or ASA, or 3.2 g/d of ibuprofen	Geriatrics: PO 2.5 – 5 mg q 4 – 6 h	Equianalgesic to oral morphine     Metabolite is hydromorphone			
Hydromorphone [C II] Dilaudid	1.5 mg	5	7.5 mg	PO: 1 - 4 mg q 4 - 6 h IV: 0.5 - 2 mg q 2 - 3 h IM/SC: 1 - 4 mg q 4 - 6 h Rectal: 3 mg q 6 - 8 h	Geriatrics: PO 1 – 2 mg q 4 – 6 h IV 0.5 – 1 mg q 4 – 6 h	Infusion at rates > 50 mg/h as- sociated with myoclonus due to accumulation of hydromorphone-3- glucuronide			
Levorphanol [C II] Levo-Dromoren	2 mg	18	2 mg (acute) 1 mg (chronic)	PO: 4 mg q 6 - 24 h SC : 1 - 2 mg q 6 - 8 h	Geriatrics: May accumulate	Doses are for single dose adminis- tration, not repeated dosing     Availablity uncertain			
Methadone [C II] Dolophine, Methadose, generics	10 mg	.5	5 mg	PO: 5 mg q 6 – 8 h IV: 10 mg q 6 – 8 h	Geriatrics: May accumulate	To chronic pain May be more potent than equianalgesic potency listed Access for significant drug reations			
MORPHINE [C II] Avinza, Duramorph, Kadian, MS Contin (MSC), MSIR, Roxanol, others	10 mg	3	30 mg (chronic) 60 mg (acute)	PO: 10 – 30 mg q 3 – 4 h (MSC 30 – 60 mg q 12 h) (Avinza 30 mg q 24 h) (Kadian 10 - 20 mg q 12 – 24 h) IV: 2 – 10 mg q 2 – 4 h SC: 5 – 20 mg q 4 h IV/SC: infusion 0.8 – 10 mg/h up to 80 mg/h IM: 5 – 20 mg q 4 h Rectal: 10 – 20 mg q 4 h	Geriatrics: PO 10 – 30 mg q 4 – 6 h (MSC 15 – 30 mg q 8 – 12 h) IV 2 – 10 mg q 4 – 6 h	Different controlled-release preparations not interchangeable     Morphine-3- and morphine-6- glucuronide may accumulate with chronic use, especially in renal failure     May be more toxic in women, due to preferential-mediated metabolism use of glucuronidation* (estrogenmediated metabolism)     Advances in Opioid Analgesia: Maximizing Benefit While Minimizing Riski,2007.B. Eliot Cole, MD, MPA			

Oxycodone [C II] OxyContin Oxy IR Case: 1:17-md-C Percolone,Roxicodone, others Percocet,Roxicet, others (with APAP); Percodan, Roxiprin, others (with ASA)	na 12804-	DA	P Doc#	PO: 10 mg q 12 h POER 5 mg q 6 h prn PO-4F 18 - 20 mg q Q Q C PO: 1 tablet q 6 h Max: 4 g/d of APAP or ASA	Q8/1/1/10. 7a.af.9. Page	Di#ta362718 for rescue dosage				
Combunox (with ibuprofen)	NA		5 mg	PO: 1 tablet Max: 4 tablets/24 h for 7 d		• For short-term (≤ 7d) management of acute pain				
Oxymorphone [C II] Numorphan	1 mg	10	10 mg (rectal)	IV: 0.5 mg initially SC/IM: 0.5 mg initially, 1 – 1.5 mg q 4 – 6 h Rectal: 5 mg q 4 – 6 h		5 mg rectal suppository = 5 mg IM morphine				
Opana	NA		10 mg	PO: 10 - 20 mg q 4 - 6 h	Geriatrics: Use caution	For moderate to severe acute pain				
Opana ER	NA		10 mg	PO: 5 mg q 12 h initially, titrate at 10 mg q 12 h q 3 – 7 d	Geriatrics: Use caution	For moderate to severe chronic pain				
PARTIAL MU AGONISTS	PARTIAL MU AGONISTS									
Buprenorphine [C V] Buprenex	0.3 mg		NA	IM/IV over 2 min: 0.3 mg q 6 h prn Repeat 1x (0.3 mg) in 30 – 60 min if needed	Geriatrics: Use caution	May precipitate withdrawal symptoms in patients physically dependent on mu opioids     Partially reversed by naloxone; use cautiously in respiratory-compromised patients				
KAPPA AGONISTS/MU ANTAGONISTS	(analgesi:	ı limit	ed by dose-rel	ated ceiling effect; concu	ment use with mu aganists may precip	itate abstinence/withdrawal symptoms)				
Butorphanol [C IV] Stadol NS	2 mg		NA	IV: 0.5 – 2 mg q 3 – 4 h IM: 1 – 4 mg q 3 – 4 h NS: 1 mg (1 spray in 1 nostril), another 1 mg in 30 – 60 min if needed; may repeat dose sequence in 3 – 4 h	Geriatrics: IV/IM — one-half of usual dose; double usual dosing interval NS — 1 mg initially, allow 90 – 120 min to elapse before deciding a second 1 mg dose	Generally used as nasal spray Use with pure agonist can result in withdrawal symptoms and seizures Not recommended for long-term use Has psychomimetic effects; elderly more likely to suffer from hallucinations and confusion Partially reversed by naloxone				
Nalbuphine <i>Nubain</i> , generics	10 mg		NA	IM/IV/SC: 10 mg/kg q 3 – 6 h Max: 20 mg/dose, 160 mg/d		Use with pure agonist can result in withdrawal symptoms and seizures     Not recommended for long-term use     Elderly more likely to suffer from hallucinations and confusion     Partially reversed by naloxone				

#### NOTE:

- · SEE PRODUCT LABELING FOR COMPLETE PRESCRIBING INFORMATION.
- · Any CNS depressant, including alcohol, can increase an opioid's effect and should not be used in conjunction with an opioid.
- · Substantial interindividual variability in patient sensitivity to analgesic effects of opioids.
- Geriatric: Analgesic CNS side effects may be particularly prominent, especially with polypharmacy. Referral for interventional techniques often helpful.
- · Opioids should be used cautiously in patients with impaired respiration, bronchial asthma, increased intracranial pressure, and renal and/or hepatic impairment.

#### Routes of Administration (consider indication and/or availability):

- · Buccal/sublingual: easy to use, rapid absorbtion, alternative if swallowing is problematic.
- IM: painful administration, wide fluctuation in absorption, rapid falloff of action.
- Intraspinal (neuraxial or subdural and epidural): useful to enhance benefit to side effect ratio, especially if intractable lower-body pain or intolerable side effects with other routes; co-administration of non-opioid with opioid analgesic(s) can achieve profound analgesia without motor, sensory, or sympathetic blockade.
- IV: bolus most rapid onset of action, infusion slower onset and peak effect, steady blood levels.
- PCA: infusion pump allows patient control over pain experience, adjusts for variations in therapeutic response.
- . PO: convenient, flexible, no skin puncture and risk of infection, steady blood levels.
- · Rectal (suppository): alternative if PO unacceptable.
- \* Transdermal: easy to use; steady absorpbtion; few side effects.

#### Table 10. Risk Management Strategies to Minimize Medication Abuse and Enhance Patient Monitoring

- Formal written agreement with patient, after detailed consent discussion, outlining clinician's policy for:
- Providing controlled prescription drug;
- Consequences of problematic drug-related behavior;
- ° Criteria for exiting opioid therapy.
- Obtain all prior health records and permission to contact healthcare providers prior to prescribing.
- Prescription of long-acting drug in appropriate quantities for specific duration of time.
- Prescription of rescue medication not to exceed more than 2 doses in 24 hours.
- Only one specified pharmacy to fill prescriptions, with permission to contact.
- No early refills and no replacement of lost prescription without documented/confirmed loss.
- Frequent patient appointments, bringing filled prescriptions for unannounced pill counts.
- Baseline urine drug screen followed by unannounced future screens.
- Require non-opioid therapies as determined, including psychotherapy or referral to addiction medicine specialist if patient at risk or exhibits aberrant behaviors.
- Permission for others (e.g., spouse, family, friends) to give feedback to physician; consider sincerely expressed concerns.
- In states with electronic prescription monitoring/tracking, initial query of database and at regular intervals; respond/follow-up any unsolicited report

After: Fine PG, Portenoy RK. A Clinical Guide to Opioid Analgesia. New York: MCGraw-Hill Company, Inc.; 2004.

## Some Online Resources for Pain Management Information

Alcohol and Drug Abuse Institute Library, University of Washington http://lib.adai.washington.edu

Agency for Healthcare Research and Quality (AHRQ) http://www.ahrq.gov

American Academy of Pain Medicine http://www.painmed.org

American Pain Foundation http://www.painfoundation.org

American Pain Society http://www.ampainsoc.org

American Society of Addiction Medicine http://www.asam.org/

Chronic Pain Newtork thhp://www.chronicpain.network.com

Beth Israel-Pain Medicine & Palliative Care

http://www.StopPain.org

Drug Enforcement Administration http://www.usdoj.gov/dea

**Emerging Solutions in Pain** 

http://www.emergingsolutionsinpain.com/

Federation of State Medical Boards of the United States http://www.medsch.wisc.edu/painpolicy/

Institute for Clinical Systems Improvement (ICSI) http://www.icsi.org

International Association for the Study of Pain http://www.iasp-pain.org/

Johns Hopkins-Center for Cancer Pain Research/Pain Site http://www.cancerpain.ihmi.edu/

Joint Commission on Accreditation of Healthcare Organizations (JCAHO) http://www.jcaho.org/

Mayo Clinic Pain Management Center

http://www.mayoclinic.com/findinformation/diseasesandconditions/index.cfm

MD Anderson Pain Site

http://www.mdanderson.org/topics/paincontrol/

MEDLINEplus: Pain

http://www.nhm.nih.gov/medlineplus/pain.html

National Foundation for the Treatment of Pain http://www.paincare.org/

National Initiative for Pain Control (NPIC)

http://www.painedu.org/nipc.asp

National Pain Education Council http://www.npecweb.org/

National Pain Foundation

http://www.NationalPainFoundation.org

Pain.com http://www.pain.com

Pain EDU http://www.painedu.org

Pain and Policy Studies Group

http://www.medsch.wisc.edu/painpolicy/

Partners Against Pain http://www.partnersagainstpain.com

Practitioners' Manual (2006), Informational Outline of Controlled Substances Act

http://www.deadiversion.usdoj.gov/pubs/manuals/index.html

Substance Abuse and Mental Health Services Administration (SAMHSA) http://www.kap.samhsa.gov

TALARIA: Hypermedia Assistant for Cancer Pain Management http://www.talaria.org/

# Case: 1:17-md-02804-DAP Doc #: 2299-2 Filed: 08/14/19 9 of 9. PageID #: 362720

**Drug Abbreviations** 

APAP acetaminophen (N-acetyl-p-aminophenol)

ASA acetylsalicyclic acid

COXIB cyclooxygenase selective inhibitor

MAOI nonoamine oxidase inhibitor

NSAID non-steroidal anti-inflammatory drug

PCA patient-controlled analgesia

SSRI selective serotonin reuptake inhibitor

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#### Disclaimer

Opioids have been shown to be a proper and effective treatment for selective patient populations with acute, cancer related, and chronic non-cancer pain. The purpose of these guidelines is to provide information for primary care physicians and other healthcare providers about the current use of opioids in pain management.

This Guideline attempts to define principles of practice that should produce high-quality patient care. It focuses on the needs of primary care practice but also is applicable to providers at all levels.

This Guideline should not be considered exclusive of other methods of care reasonably directed at obtaining the same results. The ultimate judgment concerning the propriety of any course of conduct must be made by the clinician after consideration of each individual patient situation.



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